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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/245,625 02/05/99 BURCH

R BUR-020

EXAMINER

HM12/0509

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WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/245,625

Applicant(s)

BURCH ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Receipt of request for extension of time (granted). The request filed on 3-30-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/245,625 is acceptable and a CPA has been established. An action on the CPA follows. Claims 1-22 and 25-29 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch (5,433,226; hereafter '226) in combination with Hill et al (5,098,711; hereafter '711).

Applicants claim a fiber and methods of making the fiber where a fiber having a segmented core of soft and hard segments is impregnated with a chemotherapeutic agent such as penicillin, sodium fluoride, stannous fluoride, or chlorhexidine.

'226 teaches dental floss fibers having a segmented core of hard and soft segments made of the compounds of the instant claims. '226 also teaches that this dental floss has a break elongation and tensile strength within applicants' ranges and that the fibers are in the form of multiple strands or filaments. '226 does not teach impregnating these dental floss fibers with a chemotherapeutic agent.

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'711 is relied upon for teaching multiple stranded or filamented nylon dental floss loaded with chemotherapeutic agents such as penicillin, sodium fluoride, stannous fluoride, or chlorhexidine prepared by dipping the floss into an agitated bath containing the therapeutic agent.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '226 and '711 with expectation of success, since both the floss of '226 and that of '711 utilize polymer fibers in the form of multiple strands or filaments, and the motivation that the antimicrobial agents of '711 would impart antimicrobial properties to the fibers of '226 thereby providing an effective means to deliver these antimicrobial agents to the oral cavity or gingiva and that such a floss would accommodate and clean the spacings of different dimensions between teeth while maintaining strength.

Response to Arguments

3. Applicant's arguments filed 3-30-01 have been fully considered but they are not persuasive. Applicants argue that the references can not be combined because the polymers fibers have different chemical structures and consequently have different properties and, therefore, a *prima facie* case of obviousness has not been made.

It appears applicant's are arguing that since the chemical structures are different, the Burch and Hill are nonanalogous art. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443,

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24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references relate to dental floss compositions in the field of applicants' endeavor and are pertinent to the particular problem with which applicants are concerned; Burch teaches robust dental floss formulations that accommodate and clean the spacings of different dimensions between teeth and Hill teaches improved delivery of antimicrobial agents with dental floss where the dental floss can contain up to about 50% by weight of an active chemotherapeutic agent.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed

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invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP § 2144 - § 2144.09 for examples of reasoning supporting obviousness rejections.

In the instant, there is a reasonable expectation of success, since both the floss of '226 and that of '711 utilize polymer fibers in the form of multiple strands or filaments. The motivation to combine the references is to impart antimicrobial properties of '711 to the fibers of '226 thereby providing an effective means to deliver these antimicrobial agents to the oral cavity or gingiva and that such a floss would accommodate and clean the spacings of different dimensions between teeth while maintaining strength.

Applicants also argue that combination of the references does not produce applicants' invention as Hill allegedly does not teach that chemotherapeutic agents are imbibed within the nylon dental floss.

In response, it is submitted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the term "imbibed" does not differentiate how the fiber is loaded with the chemotherapeutic agent. "Imbibed" is defined by Merriam-Websters Collegiate Dictionary 10th Edition as "to absorb or assimilate moisture, gas, light, or heat." Thus, imbibed does not distinguish how the fiber is loaded with the agent, merely that is loaded with the agent.

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Applicants further argue that the instant results are unexpected, since Example 1 of the specification shows that a conventional dental floss takes up 385 ppm of fluoride and the instant spandex floss takes up 2300 ppm of fluoride, the results are unexpected and the rejection should be withdrawn.

First, it is unknown whether the "conventional dental floss" compared in Example 1 is the same dental floss of Hill. Therefore, it is unclear whether the spandex dental floss would absorb more fluoride than the dental floss of Hill. Second, the scope of the claims is not commensurate with the scope of example 1. Example 1 utilizes spandex and sodium fluoride, while the claims are directed to an elastomeric polymer and a chemotherapeutic agent. Thus, it is unclear whether the results indicated in example 1 are applicable to all elastomeric polymers and all chemotherapeutic agents.

Conclusion

4. This is a CPA of applicant's earlier Application No. 09/245,625. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the


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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
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May 5, 2001